PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re the Application of:

ETTER

Serial No.: 09/469,733

Filed: December 21, 1999

Atty. File No.: 42830-00060

For: "PARTICULATE INSULIN-CONTAINING PRODUCTS AND METHOD OF MANUFACTURE"

Group Art Unit: 1653

Examiner: F. T. Moezie

REPLY TO OFFICE ACTION
(37 C.F.R. § 1.111)

CERTIFICATE OF MAILING

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO ASSISTANT COMMISSIONER FOR PATENTS, WASHINGTON, DC 20231 ON February 28, 2002.

MARSH FISCHMANN & BREYFOGLE, LLP

BY: _____
Michelle L. Wyss

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

This communication is responsive to an Office Action dated August 28, 2001, identified as Paper No. 9. Based on the amendments and remarks presented below, reconsideration and further examination are requested.

AMENDMENTS

Please enter amendments to the application as follows:

In the Claims:

Kindly amend the claims by changing Claims 1, 14, 18, 23, 35, 38, 46 and 47, without prejudice to or disclaimer of any subject matter. A clean version of the changed claims as they should appear after entry of the amendment follows on the next page, and a version of the changed claims showing changes made to the changed claims is included at the end of this communication.

CLEAN VERSION OF CHANGED CLAIMS

B1 SIC1

1. (Amended) A method for making an insulin-containing particulate product, the method comprising:

contacting an insulin-containing feed solution with a compressed anti-solvent fluid to precipitate insulin-containing particles, the feed solution including the insulin in a cosolvent system, the cosolvent system including at least a first organic solvent and a second organic solvent that are mutually soluble, the first organic solvent and the second organic solvent not being the same; and

separating the insulin-containing particles from the anti-solvent fluid.

B2 D1

14. (Amended) The method of claim 1, wherein the feed solution is free of amphiphilic materials that improve solubility of the insulin in the feed solution through hydrophobic ion pairing with the insulin.

B3 D1

18. (Amended) The method of Claim 1, wherein the cosolvent system is free of water.

B4 D1

23. (Amended) The method of claim 20, wherein the first organic solvent is miscible with water and the second organic solvent is immiscible with water.

B5 D1

35. (Amended) The method of claim 34, wherein the second solution is prepared by dissolving the acid in the second organic solvent and then dissolving the insulin in the second organic solvent.

B6 SIC12

46. (Amended) The method of claim 20, wherein the multi-component particles have a degree of encapsulation of the insulin by the polymer of greater than about 50 percent.

47. (Amended) The method of claim 20, wherein the the multi-component particles have a degree of encapsulation of the insulin by the polymer of greater than about 70 percent.